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INSTITUTIONAL REVIEW BOARD

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: Ultrasound-Guided Procedures in the Treatment of Meniscal Tears

RESEARCH STUDY #: R-1065-19

I, _____, am being asked to consent to participate in a research study led by Drs. Jay Bowen and Trevor Dyson-Hudson. Other persons who work with them as study staff may be asked to help them. I understand that taking part in this study is completely voluntary; I do not have to be part of this study unless I choose to be. I am free to leave the study at any time if I change my mind. All research studies carried out at Kessler Foundation are covered by the rules of both the Federal Government and Kessler Foundation.

The Information provided may contain words I do not understand. I will ask the study doctor or the study staff to explain any words or procedures I do not understand.

The table below contains a brief summary of key information about this research study. Additional information can be found throughout this document.

Study Summary	
Why is this research being done?	The purpose of this research study is to determine the safety and effectiveness of two different treatments for meniscal tears (a type of damage in the knee) in active-duty military personnel. One treatment is called micro-fragmented adipose tissue (MFAT) injection, which involves taking fatty tissue from one part of the body, breaking it up, and injecting it into another part of the body to aid in cushioning and healing. The other treatment is salt solution (saline) injection.
How long does the study last?	This study will last for up to 12 months. It will involve up to 7 visits. The initial screening and treatment visits could each take up to 2-3 hours. The remaining follow-up visits will be done either over the phone, online, or in the clinic and could take up to 1 hour.
What will happen during this research study?	I will be assigned by chance, like the flip of a coin, to one of two treatment procedures. For one of the treatment procedures, fat will first be harvested from my abdomen and then prepared using a special device. This fat will then be injected into my knee using an ultrasound device to guide the injection to the right part of my knee. For the other treatment procedure, a saline solution will be injected into my knee using ultrasound guidance. After each procedure, I will be given a set of exercises that I will perform periodically over the remainder of the study. I will be asked to complete physical

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	examinations, questionnaires, and ultrasounds for follow-up of up to one year after the procedure.
What risks are associated with participating in this study?	The risks associated with this study include pain, bruising, bleeding, and infection at the harvest and injection sites. Additional risks are discussed on page 7 of this consent form.
What are the benefits of participating in this research study?	The benefits of participating in this study may be less knee pain and better knee function without the need for surgery. However, I may receive no personal benefit from taking part in this study.
What other options are available to me if I choose not to participate in this study?	Participation in this study is completely voluntary. If I choose not to participate in this study, there will be no effect on my medical care, military/employment status, or access to benefits to which I am otherwise entitled.

The following sections offer more detail about the study.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to determine how safe and effective two treatments are for meniscal tears in active duty military personnel. One treatment is trephination with micro-fragmented adipose tissue (MFAT) injection, and the other is trephination with saline injection. *Trephination* is the process of needling the damaged tissue to promote healing. The meniscus does not have a great blood supply, so the idea behind trephination is to create small pathways in the meniscus that allows healing factors to enter the meniscus and heal the damaged tissue. These "pathways" will be filled in with either micro-fragmented adipose tissue or normal saline. Micro-fragmented adipose tissue injection is a treatment technique that uses a person's fat tissue (referred to as "adipose" tissue or "lipoaspirate") to fill joint, muscle, ligament, and/or cartilage defects, like those associated with meniscal tears. The goal of MFAT and saline injections is stimulation of tissue healing that are believed to be the cause of knee pain and dysfunction. The procedures are discussed in greater detail below.

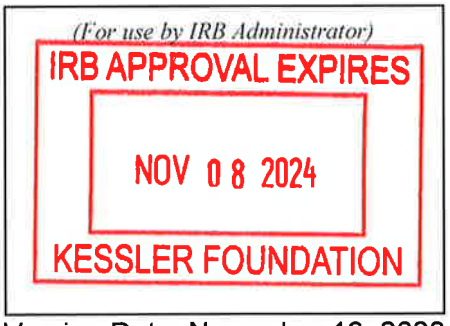
WHAT WILL HAPPEN DURING THIS RESEARCH STUDY?

The procedures will be performed at the New Jersey Regenerative Institute in Parsippany, NJ. A table summarizing the various procedures is provided at the end of this section.

While I am a part of this study, I will be asked to do the following:

Screening Visit

After signing the informed consent, I will undergo a screening evaluation to ensure I meet study inclusion/exclusion criteria. I will undergo an intake evaluation and physical examination of the knees by a physician to make sure my knee pain is consistent with a meniscal tear. If I am a woman of child-bearing age, I will be required to have a urine pregnancy test prior to entry into the study. I cannot



participate in this study unless I have a negative pregnancy test.

Clinical Ultrasound:

I will be asked to undergo a clinical ultrasound examination of my knee, which will be performed by a physician. During the test I will be asked to lie on a table. A flat metal probe about two-inches across and covered with gel will be rubbed on my most painful knee while the images are reviewed for signs of injury by the doctor.

If the results of the screening procedures meet the study requirements, I will be assigned by chance (like the flip of a coin) to one of two experimental treatment procedures (described in greater detail below) and I will be asked to return to the clinic within 2 weeks to undergo the treatment for my knee pain. I should stop taking any "anti-inflammatory" medications, such as aspirin, ibuprofen, or naproxen, for 5 days prior to the procedure.

Experimental Treatments

Trephination with Saline Injection:

On the day of the saline injection, the following things will happen:

Overall, the procedure should take approximately 1 hour to complete. I will be asked to lie flat on my back on an examination table. Vital signs (blood pressure, heart rate, respiratory rate, and pain) will be monitored periodically during the whole procedure. The following procedures will occur:

- The study doctor will mark the areas of my skin where the injection will occur. The study doctor will then clean my skin with alcohol and inject a numbing medication (lidocaine) with a small needle to reduce pain during the injection of saline.
- Immediately prior to injection, the skin on the injection site will be sterilized with a cleaning solution one more time and a sterile ultrasound gel will be applied to the area. The study doctor will then use ultrasound (similar to what was done to examine my knee at the beginning of the study) to see the structures inside of my knee. This will help the study doctor know where to place the injection. The study doctor will then inject 6 mL (1 to 1 ½ teaspoons) of saline using a small (18 gauge) needle.
- Afterwards, the injection sites will be cleaned and adhesive bandages will be applied. Immediately after the injection, I will be kept in a lying down position without moving the knee for approximately 15 minutes.

As stated above, the whole saline injection treatment procedure should take approximately 1hour to complete. My blood pressure, heart rate, respiratory rate, and pain will be monitored periodically during the whole procedure.

It will be very important for me to rest the treated knee during the first 24 hours after the injection. Therefore, during the first 24 hours after treatment I should limit my load-bearing activities, such as

walking, without crutches.

Trephination with Micro-Fragmented Adipose Tissue (MFAT) Injection:

On the day of the MFAT injection, the following things will happen:

Overall, the procedure should take approximately 1.5 hours to complete. I will be asked lie flat on my back on an examination table. Vital signs (blood pressure, heart rate, respiratory rate, and pain) will be monitored periodically during the whole procedure. The following procedures will be performed:

- Fat Harvesting (aspiration of adipose [fat] tissue): While lying on the examination table, the skin overlying my abdomen, thigh, and/or buttock areas will be injected using a small needle with an anesthetic solution to numb the area. Two small cuts (incisions) will then be made with another needle and a larger volume of anesthetic solution (0.5 to 0.75 cups or 4 to 6 fluid oz.) will be injected into the fat layer to numb more of the area. Once the area is numb, my fat will be *aspirated* ("gently sucked out") with a large syringe and transferred to the processing kit to "wash" and breakdown the fat for injection. The area (for example, abdomen, thigh, etc.) will then be cleaned and band aids placed on the incisions. The sites will be covered with a dressing and tape will be placed along the sites to minimize swelling, bruising, and pain.

  The total time from fat harvesting to injection will be approximately 60 minutes.

- MFAT Injection: While the MFAT is being processed, the study doctor will mark the areas of my skin where the injection will occur. The study doctor will then clean my skin with alcohol and inject a numbing medication (lidocaine) with a small needle to reduce pain during the MFAT injection. Immediately prior to MFAT injection, the entry site will be sterilized with a cleaning solution one more time and a sterile ultrasound gel will be applied to the area. The study doctor will then use ultrasound (similar to what was done to examine my knee at the beginning of the study) to see the structures inside of my knee. This will help the study doctor know where to place the injection. The study doctor will then inject approximately 6 mL (1 to 1 ½ teaspoons) of MFAT using a small (18 gauge) needle. Afterwards the injection sites will be cleaned and adhesive bandages applied. Immediately after the injection, I will be kept in a lying down position without moving the knee for approximately 15 minutes.

As stated above, the whole MFAT treatment procedure should take approximately 1.5 hours to complete, including the harvesting and creation of the MFAT. My blood pressure, heart rate, respiratory rate, and pain will be monitored periodically during the whole procedure.

It will be very important for me to rest the treated knee during the first 24 hours after the injection. Therefore, during the first 24 hours after treatment I should limit my load-bearing activities, such as walking, without crutches.

***After the Injection Procedures*:**

Detailed, written instructions on what to do after the treatment will be provided to me, including contact numbers (24/7) for study team physicians.

I should keep the harvest and injection sites clean and dry for 24hrs. The harvest site dressing can be removed after 24 hours.

After my injection, I may experience 3-6 hours of numbness in the area of my injection due to the local anesthetic used during the procedure. I understand this is normal. When the numbness wears off, it is common to experience some pain in the area of my injection and I may have increased pain for up to 2 weeks after the procedure. This is to be expected as it will take time for my body to heal.

I should try and reduce my activities for 7 days and then slowly increase using pain as my guide. I should use crutches for walking during these 7 days. I will be provided crutches if needed. I should also avoid running and jumping activities for 4 weeks. After 4-6 weeks, I will be asked to start a progressive strengthening program. After 6-8 weeks, if there is no pain, swelling, or significant joint line tenderness, and I have near full range of motion, I will be allowed to continue with my normal activities as tolerated.

I will call the Investigators if there is extreme pain, redness or warmth over the injection site, or fever. If I have shortness of breath, then I will call 911.

Follow-up Visits

I will be asked to return to the clinic approximately 3 months, 6 months, and 12 months after the procedure. Earlier follow-up visits can be done over the phone and will be performed approximately 1 week, 1 month, and 2 months after the procedure. At each of the follow-up visits, I will be asked a series of questions regarding any changes in my health and medications, as well as a series of questions regarding my knee pain. At the 3, 6, and 12-Month Visits, I will also undergo a physical examination of my knee for signs and symptoms of pain. The follow-up visit should take approximately 1 hour to complete. Below is a table of the various procedures and when they will be performed.

Procedures	Screen	Treatment	Follow-up Visits (*phone; **in-person)					
			Week 1 Phone Follow-up	1* Month 1	2* Month 2	3** Month 3	4** Month 6	5** Month 12
Informed Consent	X							
Background Information	X							
Other Medications	X	X	X	X	X	X	X	X
Knee Pain/Medical History	X							
Knee Exam	X					X	X	X
Knee Ultrasound	X							
Treatment		X						
Adverse Events		X	X	X	X	X	X	X

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Knee Pain Questionnaires	X	X		X	X	X	X	X
Protocol Adherence Measure			X	X	X			
Post-Procedure Protocol Review			X	X	X			

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 80 people will take part in this study, with up to 35 individuals being enrolled at each of the four sites.

WHO QUALIFIES TO PARTICIPATE IN THIS STUDY?

In order to participate in this study, I must meet the following Inclusion Criteria, which will be determined at screening:

- I am between 18 and 45 years old.
- I have at least one of the following symptoms in my knee: clicking, popping, giving way, pain with pivoting or twisting, and/or pain that is occurs occasionally or irregularly.
- I have pain that can occur when my knee joint line is manipulated or compressed.
- I have pain on the outside of my knee that has persisted for at least 4 weeks despite conservative treatments, which has included anti-inflammatory or other medications for pain; physical therapy; or injections that include corticosteroids and/or hyaluronic acid.
- My knee pain during activity is at least 4 out of 10 (where 0 is "no pain" and 10 is "worst pain imaginable).
- I have MRI or arthroscopic evidence of a meniscal tear.

I would also qualify if I have been told by an orthopedic surgeon that I would be a candidate for arthroscopic partial meniscectomy.

WHAT MIGHT MAKE ME INELIGIBLE FOR THIS STUDY?

If any of the items listed below are true for me, I will tell the researcher. To ensure my privacy, I do not have to say which item or items apply to me. If I choose to tell the investigator which items are true for me, the information will not be shared with anyone.

- My knee is locked.
- I have X-Ray evidence of moderate osteoarthritis.
- I have had a prior surgery on the painful knee.
- I have any other issue with my knee that a meniscus tear that would require surgical intervention.
- I have recently (within 6 weeks) had treatment with platelet rich plasma, cortisone (oral or injection), or hyaluronic acid injection.
- I have any disease that the investigator feels would hinder treatment.
- I have a bleeding disorder, infection, pregnancy, allergy to anesthetic agents, or any other issue that would prevent me from receiving the treatment.
- I have had a cancer within the past 5 years.

Because of potential risk to the fetus, women of child bearing potential will be required to have a pregnancy test before they can enroll in this study. If I am female, and have a positive pregnancy test, I will not be enrolled.

WHAT RISKS ARE ASSOCIATED WITH PARTICIPATING IN THIS STUDY?

The study described above may involve the following risks and/or discomforts:

- Lipoaspiration (Adipose/Fat Harvest): Some of the risks of the procedure include: pain at the procedure site, bleeding, black and blue bruising, infection, skin dimpling, abdominal injury, muscle injury, or lightheadedness/fainting.
- MFAT injection and sterile saline injection procedures: immediate pain at the injection site; stiffness in the injected joint; bruising; allergic reaction to the anesthetic solution; infection from the injection; injury to a nerve and/or muscle; no relief from symptoms; worsening of symptoms; itching at the injection site; dizziness or fainting; swelling after the joint injections; and bleeding at the injection site. There is no risk of rejection or disease transmission, since the injected materials are derived from my own body.

If I become pregnant during the course of the study, I will notify the principal investigator of this fact as soon as possible since the risks to the fetus or me are unknown.

There also may be risks and discomforts that cannot be foreseen.

WHAT WILL HAPPEN IF THE RESEARCHERS LEARN NEW INFORMATION ABOUT THE STUDY?

During the course of the study, I will be told about any new findings that might affect my willingness to remain in the study.

WHAT WILL BE DONE TO PROTECT INFORMATION ABOUT ME?

Every effort will be made to maintain the privacy of my study records.

Protected Health Information

The researchers would like to use information about my health as well as information that identifies me. This information is referred to as "Protected Health Information" and is given special protections under The Federal Health Insurance Portability and Accountability Act (HIPAA) of 1996. The researchers must obtain my approval to use Protected Health Information.

If I participate in this research study, information that will be used and/or released may include the following:

- Information from my medical records, such as my diagnoses, medications or other treatments I am receiving, images (such as MRIs or other scans), reported symptoms, ability to function, and other observations made by health professionals as part of my medical care.
- Questionnaires about how I am feeling physically or emotionally.
- Results of tests of my physical function.
- Results of laboratory tests or physical examinations given for purposes of the research study.
- What study medications I have been prescribed, my use of the prescribed medication, and whether I am experiencing any problems that could be related to the study medication.
- Other observations made by researchers during the course of the research study.

Protected Health Information such as my name, address, date of birth, etc., that is stored electronically is kept in a separate system called the Subject Information Management System (SIMS). SIMS is managed using a database called REDCap. REDCap meets the requirements of laws that protect health information. Access to study data in REDCap will be restricted to members of the study team only. Data are secured by requiring multiple types of login information to reach the study database. REDCap/SIMS also tracks access to and changes made to any records. Kessler Foundation does not permit Protected Health Information to be kept electronically in documents that are not protected in this way in order to ensure my privacy and the confidentiality of my information. Hard copy documents that contain my name, phone number, address, date of birth, etc., are kept in locked cabinets that only members of the research team can access.

Sharing Protected Health Information

My health information may be shared with people and researchers at this institution and associates of the sponsor(s), university, clinic or hospital who help with the research. The researchers may share this information with other people or organizations who are in charge of the research, others who are helping the research study to be done, those who pay for the research, or those who make sure that the research is done properly.

The study team may share a copy of this approval form and records that identify me with the following people or organizations:

- The Institutional Review Board - a committee that reviews research studies for the protection of the people who participate in research.
- Auditors from Kessler Foundation, the sponsor (the Department of Defense [DoD] Defense Health Agency [DHA]) or government agencies responsible for the conduct of research to make sure the researchers are following regulations, policies, and study plans.
- Members of the study team, including Jay Bowen, DO; Trevor Dyson-Hudson, MD; Nathan Hogaboom, PhD; Nelson Hager, MD; and Shalaka Paranjpe, MS.
- Other organizations: The Geneva Foundation, The Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), The Uniformed Services University of Health Sciences (USUHS), and the Department of Defense (DoD) Defense Health Agency (DHA).

I have the right to look at my study information at the study doctor's office and to ask (in writing) for corrections of any of my information that is wrong.

If the findings from the study are published, I will not be identified by name. My identity will remain private unless its release is required by law.

Removing Approval

I can change my mind at any time and remove my approval to allow my information to be used in the research. If this happens, I must remove my approval in writing. Beginning on the date I remove my approval, no new information will be used for research. However, researchers may continue to use the information that was provided before I withdrew my approval.

If after signing this form, I want to remove my approval, I can contact the person(s) below. He/she will make sure the written request to remove my approval is processed correctly.

Trevor Dyson-Hudson, MD
Director, Center for Spinal Cord Injury Research
and Center for Outcomes and Assessment Research
1199 Pleasant Valley Way
West Orange, NJ 07052
Phone: 973-324-3576
Fax: 973-243-6824

Shalaka Paranjpe, MS
Research Coordinator
1199 Pleasant Valley Way
West Orange, NJ 07052
Phone: 973-324-6643
Fax: 973-243-6824

Approval Expiration

This approval has no expiration date. However, as stated above, I can change my mind and remove my approval at any time.

Questions should be directed to the research staff person who is reviewing this form with me. I can also call the Kessler Foundation Privacy Board – *John DeLuca, Ph.D., ABPP at (973) 324-3572.*

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WHERE ELSE CAN I FIND INFORMATION ABOUT THIS STUDY?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify me. At most, the website will include a summary of the results. I can search this website at any time using the ClinicalTrials.gov Identifier, NCT04274543, to locate this study.

WILL IT COST ANYTHING TO PARTICIPATE IN THIS STUDY?

There will be no cost to me for my taking part in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

I will not be paid for participating in this study.

WHAT WILL HAPPEN IF I AM INJURED IN THIS STUDY?

If I take part in this study, I will be exposed to certain risks of physical injury. I may request assistance from the Principal Investigator to arrange medical treatment for any physical injury that occurs as a direct result of my taking part in this study. I understand that I will be responsible for any costs associated with treatment for any physical injury that occurs while I am in this study. My health insurance carrier, managed care provider or other third party payer will be billed for the cost of my medical treatment. I will be responsible for any part of the treatment cost not paid by my insurance or managed care provider. No financial payment is offered to me in the event of physical injuries that happened as a direct result of my taking part in this study.

CAN I CHANGE MY MIND ABOUT PARTICIPATING IN THIS STUDY?

I understand that taking part in this study is my choice, and I may refuse to take part, or may stop taking part in the study at any time without penalty or loss of benefits to which I am otherwise entitled. I also understand the investigator has the right to withdraw me from the study at any time.

If I decide to withdraw for any reason, the Investigators would like to follow-up with me one more time. During this visit, study staff will perform a physical examination of my knee and I will be asked to complete some knee pain questionnaires.

WHO CAN I CONTACT FOR MORE INFORMATION?

If I have any questions about my treatment or the research procedures, I can contact:

Dr. Trevor Dyson-Hudson
Kessler Foundation, SCI Research
1199 Pleasant Valley Way
West Orange, NJ 07052
Work: 973-324-3576
Mobile (24/7): 917-838-3143

Dr. Jay E. Bowen
New Jersey Regenerative Institute
299 Cherry Hill Road, Suite 105
Parsippany, NJ 07054
Work: 973-998-8309

Dr. Nathan Hogaboom
Kessler Foundation
1199 Pleasant Valley Way
West Orange, NJ 07052
Work: 973-324-3584
Mobile: 610-585-4380

If I have concerns only regarding my **rights as someone taking part in a research study**, I may contact Donna Servidio, IRB Manager, at 1-800-648-0296, extension 6972.

I will receive a copy of this consent form if I agree to take part in this research study.

WILL INFORMATION ABOUT ME BE USED FOR OTHER RESEARCH STUDIES IN THE FUTURE?

The information collected in this research study may be useful in future research studies. The researchers may use or share my information in future research in a way that does NOT identify me without additional informed consent from me. In this situation, the researchers who are using my information do not have access to my name or other identifying information and would not know that I am the person who provided the information. If researchers wish to use or share information that can identify me, they will be required to obtain my informed consent, in writing, for the use or sharing of my information in future research.

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name:_____
_____Signature:_____

Date:_____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL

To the best of my knowledge, the participant, _____
_____, (or his /her parent/legal guardian) has understood the entire content of the above

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consent form, and comprehends the study and its risks as well. The participant's questions and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator Name:_____
_____Signature:_____

Date:_____

SIGNATURE OF WITNESS

I was present when the researcher(s) described the study to the participant (or his/her parent or legal guardian) and I am a witness to the fact that the participant (or his/her parent or legal guardian) consented to participation in this study.

Witness Name:_____
_____Signature: _____

Date:_____

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